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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte NORDINE CHEIKH, JINGDONG LIU, and VIRGINIA M.
PESCHKE

Appeal 2008-005234
Application 09/300,482
Technology Center 1600

Decided:¹ May 29, 2009

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES,
Administrative Patent Judges.

ADAMS, *Administrative Patent Judge.*

DECISION ON APPEAL

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This appeal under 35 U.S.C. § 134 involves claims 1, 11-13, 15-22, 24, 28, 30, and 31, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a nucleic acid molecule. Claim 11 is illustrative:

11. An isolated nucleic acid molecule, wherein said isolated nucleic acid molecule comprises a nucleic acid sequence selected from the group consisting of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 or complements thereof.

The Examiner relies on the following prior art references to show unpatentability:

Robert B. Russell and Geoffrey J. Barton, *Structural Features can be Unconserved in Proteins with Similar Folds*, 244 J. MOL. BIOL. 332-350 (1994).

David Gerhold and C. Thomas Caskey, *It's the genes! EST access to human genome content*, 18 BIOESSAYS 973-981 (1996).

Timothy N. C. Wells and Manuel C. Peitsch, *The chemokine information source: identification and characterization of novel chemokines using the WorldWideWeb and Expressed Sequence Tag Databases*, 61 J. LEUKOC. BIOL. 545-550 (1997).

Teresa K. Attwood, *The Babel of Bioinformatics*, 290 SCIENCE 471-473 (2000).

The rejections presented by the Examiner are as follows:

1. Claims 1, 11-13, 15-22, 24, 28, 30, and 31 stand rejected under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility.
2. Claims 1, 22, 24, and 28 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.
3. Claims 1, 22, 24, and 28 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse.

Utility:

ISSUE

Did the Examiner meet his initial burden of challenging Appellants' presumptively correct assertion of utility?

FINDINGS OF FACT

FF 1. Appellants disclose that their "invention relates to nucleic acid sequences from plant cells, in particular, nucleic acid sequences from maize and soybean plants associated with the phosphogluconate pathway in plants" (Spec. 1: 7-9).

FF 2. The phosphogluconate pathway "is one of the two major pathways in plants by which carbohydrates may be ultimately degraded into CO₂, the other being glycolysis followed by the TCA cycle" (Spec. 1: 18-21).

FF 3. Appellants disclose maize or soybean phosphogluconate pathway enzymes or fragments thereof encoded by a first nucleic acid molecule which specifically hybridizes with a second nucleic acid molecule selected

from the group consisting of a complement of SEQ ID NO: 1 through SEQ ID NO: 699 or a complement thereof (Spec. 15: 13-17; *see generally* Spec. 15: 18 - 23:11).

FF 4. According to Appellants' Specification, the disclosed sequences or ESTs "can represent copies of up to the full length [mRNA] transcript" (Spec. 8: 8).

FF 5. Appellants' Table A illustrates that SEQ ID NOs: 1-699 share some percent identity with maize or soybean nucleic acids that encode various enzymes in the phosphogluconate pathway (Spec. 224: 1 - 240: 9).

FF 6. Appellants disclose that SEQ ID NOs: 1-11 encode "a maize or soybean glucose-6-phosphate-1-dehydrogenase enzyme," "fragment thereof," or homologue thereof (Spec. 51: 3-7 and 52: 4-5).

FF 7. Appellants disclose that SEQ ID NO: 4 has 44 percent identity with a nucleic acid molecule that encodes a soybean glucose-6-phosphate 1 dehydrogenase (Spec. 224: 10; App. Br. 7).

FF 8. Appellants disclose that SEQ ID NOs: 12-103 encode "a maize or soybean 6-phosphogluconate dehydrogenase enzyme," "fragment thereof," or homologue thereof (Spec. 50: 11-12; 52: 4-5).

FF 9. Appellants disclose that SEQ ID NO: 14 has 72 percent identity with a nucleic acid molecule that encodes a maize 6-phosphogluconate dehydrogenase (Spec. 224: 24; App. Br. 7).

FF 10. Appellants' Specification discloses

In an aspect of the present invention, one or more of the nucleic molecules of the present invention are used to determine the level (i.e., the concentration of mRNA in a sample, etc.) in a plant (preferably maize or soybean) or pattern (i.e., the kinetics of expression, rate of decomposition, stability profile, etc) of the expression of a protein encoded in part or

whole by one or more of the nucleic acid molecule[s] of the present invention.

(Spec. 80: 6-10.) In addition, Appellants' Specification discloses that "[i]t is understood that one or more of the nucleic acids of the present invention may be introduced into a plant cell and transcribed using an appropriate promoter with such transcription resulting in the cosuppression of an endogenous phosphogluconate pathway enzyme" (Spec. 111: 19-21). In this regard, Appellants' Specification discloses that "[t]he objective of the antisense approach is to use a sequence complementary to the target gene to block its expression and create a mutant cell line or organism in which the level of a single chosen protein is selectively reduced or abolished" (Spec. 112: 1-3).

FF 11. Appellants disclose that "[i]t is understood that the activity of a phosphogluconate pathway enzyme in a plant cell may be reduced or depressed by growing a transformed plant cell containing a nucleic acid molecule whose non-transcribed strand encodes a phosphogluconate pathway enzyme or fragment thereof" (Spec. 113: 1-4).

FF 12. Wells teaches that the chemokines family of proteins has been divided into the CXC, CC, and C subfamilies "depending on the spacings of highly characteristic cysteine residues within their amino-terminal regions" (Wells, 545: col. 2, ll. 20-22). Wells teaches that

In addition to the conserved cysteine motif described above, the CC chemokines share other clear sequence similarities such as a C-terminal helix and conserved hydrophobic sequences in the first and third beta sheet. These features make the identification of novel chemokines in sequence databases relatively easy because even though the overall sequence identity levels between chemokines may be as low as 20%, the cysteine

spacings and hydrophobicity may still be used to detect novel chemokine sequences.

(Wells, 545: col. 2, l. 28 - 546: col. 1, l. 6.) Therefore, Wells teaches that despite an overall sequence identity level as low as 20%, the features of the sequences may still be used to detect novel chemokine sequences.

FF 13. Gerhold discusses ESTs and teaches that “one can best find proteins related to *ras*, for example, using a protein or DNA sequence query” (Gerhold 975: col. 2, ll. 17-19).

PRINCIPLES OF LAW

The “utility requirement” originates with the provision of 35 U.S.C. § 101 that a patent may be obtained on “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” An inquiry by the PTO into whether a claimed invention satisfies the utility requirement typically has two distinct prongs. First, the PTO must determine whether the patent applicant has asserted a specific and substantial utility for the claimed invention. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). Second, the PTO must ascertain whether there is any evidence that one of ordinary skill in the art would reasonably doubt the invention’s asserted utility. *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995).

[T]he PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. . . . Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention’s asserted utility. *See In re Bundy*, 642 F.2d 430, 433.

In re Brana, 51 F.3d at 1566.

ANALYSIS

Claim 11 is drawn to an isolated nucleic acid molecule. The isolated nucleic acid molecule of claim 11 comprises a nucleic acid sequence selected from the group consisting of SEQ ID NOS: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 or complements thereof.

The Examiner finds that the claimed nucleic acids are not supported by a specific asserted utility because none of the disclosed uses of the nucleic acids are specific (Ans. 4). We disagree.

Appellants' Specification discloses that the nucleic acids of each of the SEQ ID NOS recited in claim 11 encodes a protein having a significant sequence similarity to an enzyme in the phosphogluconate pathway (FF 5). For example, the Specification discloses that SEQ ID NOS: 4 and 14 have 44 and 72 percent identity with a soybean glucose-6-phosphate and maize 6-phosphogluconate dehydrogenase respectively (FF 1-3, 7, and 9). Soybean glucose-6-phosphate and maize 6-phosphogluconate dehydrogenase are enzymes involved in the phosphogluconate pathway.

Appellants' Specification further discloses that the inventive nucleic acid molecules can be used, inter alia, to determine the concentration of mRNA in a sample, to determine the expression pattern of a protein encoded in part or whole by one or more of the nucleic acid molecules, and to inhibit expression using antisense approaches (FF 10). As Appellants explain, inhibiting expression using antisense approaches will result in a transformed plant cell wherein the activity of a phosphogluconate pathway enzyme is reduced or depressed (FF 11).

There is no evidence on this record that Appellants' claimed nucleic acid molecules would not be useful in determining the mRNA concentration of a phosphogluconate pathway enzyme, expression pattern of a phosphogluconate pathway enzyme in a sample, or in antisense approaches to prevent or reduce the function of a phosphogluconate pathway enzyme gene. In addition, there is no evidence on this record that a full length sequence or that further research would be required to perform these utilities.

The *Fisher* court held that measuring mRNA concentration or expression pattern of an uncharacterized EST does not provide a specific and substantial utility that satisfies § 101. See *Fisher*, 421 F.3d at 1368 and 1373-74. In this case, however, the ESTs corresponding to the SEQ ID NOs recited in claim 11 are disclosed to have significant similarity to known enzymes with known functions. In our view, the similarity of the claimed nucleic acids to products having known functions is adequate to support the utility of the claimed nucleic acids as research tools to measure gene expression or to reduce expression of the encoded product. Accordingly, we disagree with the Examiner's assertion that the claimed invention lacks a patentable utility (Ans. 4-6).

Further, while Appellants assert that their Specification provides a statistically relevant correlation between the claimed nucleic acid sequences and the respective enzymes (App. Br. 7-8), the Examiner asserts that Appellants' reliance on "percentage sequence similarity of less than 100% does not provide sufficient guidance or support to one skilled in the art so as to determine what biochemical activity or properties the instantly claimed subject matter would have" (Ans. 5). In support of this finding, the

Examiner asserts that Attwood, Gerhold, Wells, and Russell document the “unpredictability of the relationship between sequence and function” (Ans. 6). The Examiner does not, however, direct our attention to any portion of the cited references that support this position.

Our review of the cited references leads us to conclude that they do not support the Examiner’s position. For example, Wells teaches that the chemokines family of proteins has been divided into the CXC, CC, and C subfamilies “depending on the spacings of highly characteristic cysteine residues within their amino-terminal regions” (FF 12). Wells teaches that

In addition to the conserved cysteine motif described above, the CC chemokines share other clear sequence similarities such as a C-terminal helix and conserved hydrophobic sequences in the first and third beta sheet. These features make the identification of novel chemokines in sequence databases relatively easy because even though the overall sequence identity levels between chemokines may be as low as 20%, the cysteine spacings and hydrophobicity may still be used to detect novel chemokine sequences.

(*Id.*) Therefore, Wells teaches that despite an overall sequence identity level as low as 20%, the features of the sequences may still be used to detect novel chemokine sequences. Further, the Gerhold paper discusses ESTs and teaches that “one can best find proteins related to *ras*, for example, using a protein or DNA sequence query” (FF 13).

Accordingly, we find that the evidence relied upon by the Examiner fails to support the Examiner’s rejection on this record.

CONCLUSION OF LAW

For the foregoing reasons we find that the Examiner has failed to meet his burden of challenging Appellants' presumptively correct assertion of utility. *Brana*, 51 F.3d at 1566.

Accordingly, the rejection of claims 1, 11-13, 15-22, 24, 28, 30, and 31 under 35 U.S.C. § 101 as lacking a patentable utility and under the enablement provision of 35 U.S.C. § 112, first paragraph based on the finding of lack of utility is reversed.

Written Description:

ISSUE

Have Appellants provided an adequate written description of their claimed invention?

FINDINGS OF FACT

FF 14. The Examiner finds that Appellants' Specification "discloses SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619" (Ans. 7).

FF 15. The Examiner finds that Appellants' "claims 11-13, 15-22, 30, and 31 drawn to a substantially purified nucleic acid molecule consisting of SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569 and 619 or complement thereof meet the written description provision of 35 USC [sic] 112, first paragraph" (*id.*).

PRINCIPLES OF LAW

“The burden of showing that the claimed invention is not described in the application rests on the PTO in the first instance.” *In re Edwards*, 568 F.2d 1349, 1354 (CCPA 1978).

The “written description” requirement . . . serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. . . .

The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.

Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005). *See Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006) (“[E]xamples are not necessary to support the adequacy of a written description[;] . . . the written description standard may be met . . . even where actual reduction to practice of an invention is absent.”).

ANALYSIS

The Examiner finds that Appellants’ Specification

does not teach or disclose any open reading frames (ORFs) that are contained within SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 such that a maize or soybean phosphogluconate pathway enzyme or fragment thereof would be obtained by expression of an isolated nucleic acid molecule as instantly claimed.

(Ans. 7.) Based on this reasoning the Examiner concludes that “one of skill in the art would not recognize that applicants were in possession of a purified nucleic acid molecule that encodes a maize or soybean phosphogluconate pathway enzyme or fragment thereof as instantly claimed” (*id.*). We are not persuaded.

Each of claims 1, 22, 24, and 28 requires that the claimed nucleic acid *comprise* a nucleic acid defined by SEQ ID NO. The Specification describes the nucleic acid sequence – the chemical structure – of the SEQ ID NOs that define the claimed nucleic acids. The Specification provides evidence that the nucleic acid sequences have significant similarity to known genes and, based on that structural similarity, discloses that the SEQ ID NOs recited in the claims encode specific protein products. The Examiner has not provided sufficient evidence to support a conclusion that the Specification’s disclosure is factually wrong.

Therefore, the Examiner’s finding that Appellants’ Specification fails to teach an open reading frame within SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 is not sufficient in and of itself to conclude that Appellants’ claimed invention lacks written descriptive support. As Appellants point out “[t]he fact that the claims at issue are intended to cover molecules that include the recited sequence joined with additional sequences, or complements of the recited sequence, does not mean that Appellants were any less in possession of the claimed nucleic acid molecules” (App. Br. 14).

Accordingly, the evidence of record fails to establish that Appellants’ claims lack written descriptive support for nucleic acid molecules that encode a maize or soybean phosphogluconate pathway enzyme or fragment thereof that *comprises* a nucleic acid identified by SEQ ID NO.

CONCLUSION OF LAW

Appellants provided an adequate written description of their claimed invention.

The rejection of claims 1, 22, 24, and 28 under the written description provision of 35 U.S.C. § 112, first paragraph is reversed.

Enablement:

ISSUE

Have Appellants provided an enabling description of their claimed invention?

FINDINGS OF FACT

FF 16. The Examiner finds that because the nucleic acids identified in the claims by SEQ ID NO each comprise “several ATG codons, any of which may be a possible start site for translation into a peptide, but no ORF has been disclosed as that encoding the claimed protein” it would require “trial and error experimentation to determine how to make a maize or soybean phosphogluconate pathway enzyme or fragment using the instantly claimed purified nucleic acid molecules” (Ans. 8-9).

PRINCIPLES OF LAW

Enablement is a question of law, based on underlying findings of fact. *See, e.g., In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988).

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

To satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, a patent application must adequately disclose the claimed invention so as to enable a person skilled in the art to practice the invention at the time the application was filed without undue experimentation. *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999). However, “nothing more than objective enablement” is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971). “[T]here must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and how to use the invention as broadly as it is claimed.” *In re Vaack*, 947 F.2d 488, 496 & n. 23 (Fed. Cir. 1991). Therefore, it

is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

In re Marzocchi, 439 F.2d at 224.

ANALYSIS

The Examiner’s reasoning is based on the premise that the nucleic acids recited by SEQ ID NO have not been shown to encode a maize or soybean phosphogluconate pathway enzyme or fragment thereof. Appellants’ Specification, however, states that the nucleic acid sequences of the SEQ ID NOs recited in the claims have significant similarity to known genes and, based on that structural similarity, the nucleic acids encode

specific protein products. The Examiner has not provided sufficient evidence to support a conclusion that the Specification's presumptively accurate disclosure is wrong. The Examiner's rejection therefore is not supported by a preponderance of the evidence on this record.

Therefore, the Examiner's finding that Appellants' Specification fails to teach an open reading frame within SEQ ID NOs: 1, 4, 14, 27, 225, 298, 311, 356, 569, and 619 is not sufficient in and of itself to conclude that Appellants' Specification lacks an enabling description of the claimed invention.

CONCLUSION OF LAW

Appellants provided an enabling description of their claimed invention.

The rejection of claims 1, 22, 24, and 28 under the enablement provision of 35 U.S.C. § 112, first paragraph is reversed.

REVERSED

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